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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,266	06/20/2003	Fumitoshi Asai	03337C/HG	7488
1933	7590	09/28/2005	EXAMINER	
FRISHAUF, HOLTZ, GOODMAN & CHICK, PC 220 5TH AVE FL 16 NEW YORK, NY 10001-7708			KWON, BRIAN YONG S	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,266	ASAI ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/20/03 and Tele. Interview on 08/26/05.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 6-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/02/03, 06/02/04, 06/02/05, 06/20/03</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group (A), Claims 1-5, drawn to a process of a pharmaceutical composition comprising 2-acetoxy-5-(alpha-cyclopropylcarbonyl-2-fluorobenzyl)-4-5,6,7-tetrahydrothieno[3,2-c]pyridine and aspirin.

Group (B), claim(s) 6-11, drawn to a method of treating/preventing disease caused by thrombus or embolus comprising administering said combination.

Group (C), claim(s) 12-14, drawn to a method of to a method of treating a patient undergoing stenting, angioplasty and/or preventing restenosis comprising administering said combination.

The inventions listed as Groups A-C do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature linking groups A-C appears to that they all relate to a 2-acetoxy-5-(alpha-cyclopropylcarbonyl-2-fluorobenzyl)-4-5,6,7-tetrahydrothieno[3,2-c]pyridine and aspirin. However, the claimed combinations are known in the art (US 6509348, see column 4, lines 18-30 and 38-42; column 31, lines 32-37). Therefore, the technical feature linking the inventions of groups

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A-C does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Accordingly, Groups A-C are not linked by the same or a corresponding special technical feature as to form a single general inventive concept.

2. During a telephone conversation with Marshall J. Chick on August 26, 2005 a provisional election was made to prosecute the invention of Group I, claims 1-5.

Affirmation of this election must be made by applicant in replying to this Office action.

Claims 6-14 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

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Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Ogletree (US 6509348).

Ogletree expressly teaches ADP receptor blocking antiplatelet drug (i.e., CS-747 which is 2-acetoxy-5-(alpha-cyclopropylcarbonyl-2-fluorobenzyl)-4-5,6,7-tetrahydrothieno[3,2-c]pyridine) or pharmaceutically acceptable salts thereof in combination with thromboxane A2 receptor antagonist and aspirin, wherein the ratio of said ADP receptor blocking antiplatelet drug and aspirin is within the range from about 50:1 to about 0.51, preferably from about 25:1 to about 1:1 (see column 4, lines 18-30 and 38-42; column 31, lines 32-37) .

Since the interpretation of the instant claims allow for the inclusion of any other unspecified ingredients even in major amounts in said composition, the referenced combination anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 4 and 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Ogletree (US 6509348) in view of Koike et al. (US 5288726).

The teaching of Ogletree has been discussed in above 35 USC 102(e) rejection.

Koike teaches compounds represented by formula (I) including 2-acetoxy-5-(alpha-cyclopropylcarbonyl-2-fluorobenzyl)-4-5,6,7-tetrahydrothieno[3,2-c]pyridine, wherein said compounds are prepared in pharmaceutically salts thereof including maleate and hydrochloride (abstract; column 13, lines 43-63; column 22, line 19 and Example 23).

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The teaching of Ogletree differs from the claimed invention in the use of 2-acetoxy-5-(alpha-cyclopropylcarbonyl-2-fluorobenzyl)-4-5,6,7-tetrahydrothieno[3,2-c]pyridine in the specific salt form, namely hydrochloride or maleate. To incorporate such teaching into the teaching of Ogletree, would have been obvious in view of Koike who teaches the preparation of 2-acetoxy-5-(alpha-cyclopropylcarbonyl-2-fluorobenzyl)-4-5,6,7-tetrahydrothieno[3,2-c]pyridine in the form of maleate and hydrochloride salt. One having ordinary skilled in the art would have been motivated to select the claimed compounds in maleate or hydrochloride salt with reasonable expectation of success that preparation of said composition in maleate and hydrochloride salt form would not significantly alter the analogous properties of compound of the reference due to close structural similarity of the compounds. One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

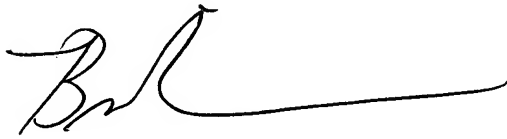
6. No Claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (571) 273-8300.

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Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon
Patent Examiner
AU 1614

A handwritten signature in black ink, appearing to be 'BK' followed by a long horizontal stroke.